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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sergey Popov

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DANIEL J SWIRSKY
55 REUVEN ST.
BEIT SHEMESH, 99544
ISRAEL

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,538	Applicant(s) POPOV, SERGEY	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 16 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3-5-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

There are numerous typographical and grammatical errors throughout the claims and specification. The list below is not intended to be exhaustive. Examiner requests Applicant's help in finding and correcting all of these errors.

Claim 45 is objected to because of the following informalities: the term "wherein there are" on line 1 is not grammatically correct. Appropriate correction is required.

Claim 47 objected to because of the following informalities: the term "...a carrier attachment means allowing removable attaching said carrier to said cannula." On lines 2-3 is not grammatically correct. . Appropriate correction is required.

Claim 54 is objected to because of the following informalities: "said dilating surfaces are faced the walls" is not grammatically correct. Appropriate correction is required.

Claim 55 objected to because of the following informalities: The term "performing a through relative small primary opening" is not grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are many problems with the claims, including typographical and grammatical errors, that make it difficult, if not impossible, for the examiner to understand the scope of the claims. The list of rejections below is not exhaustive and Examiner requests Applicant's help in correcting any other problems they have found.

Claim 39 recites the limitations "the axial limits" in line 16, "the transversal dimensions" in line 17, "the outer diameter" in line 19. There is insufficient antecedent basis for this limitation in the claim.

Further regarding Claim 39, there are numerous typographical errors that make the claim limitations difficult to understand. For example the passage "said dilating surfaces are faced the walls of said primary opening" on lines 16-17 is not grammatically correct. The passage on lines 19-21 states: "the outer diameter of said passageway portion to provide inserting said dilating portion into said primary opening with an insignificant resistance offered by the body tissues and without substantial stretching said opening". This passage is grammatically incorrect and provides little definition to what Applicant intends to include in the claim's scope.

The terms "considerably less" in claim 39 and 54 and 55, "insignificant resistance" in claim 39 and 54 and 55 and "without substantial stretching" in Claim 39 and 54 and 55 are relative terms which renders the claim indefinite. The terms "considerably", "insignificant", and "substantial" are not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding Claim 44, it is not clear what is meant by the term “based on”.

Claim 49 states "said dilating members" however claim 40 only requires “at least one dilating member. It is unclear if the claim requires one or more than one dilating member.

Claim 51 recites the limitations "said dilating surfaces movement" in line 1 and “the transversal direction” in line 2. There is insufficient antecedent basis for these limitations in the claim.

Claim 53 recites the limitations "...made as a cylinder containing said fluid in the form of a liquid, communicated with said balloon", and “adapted to forcing out”, and “and to permitting said liquid”, which are not grammatically correct. The scope of the limitation is unclear.

Claim 54 recites the limitation "the location at the level" in line 4 There is insufficient antecedent basis for this limitation in the claim.

In claim 54, the limitation “a dilating portion of changeable geometry disposed adjacent to said distal portion proximally of it and distally of said passageway portion,” is unclear because it is wordy and grammatically incorrect.

In Claim 54, the limitation "wherein said transversal dimensions of said dilating portion are effectively bigger than its correspondent dimensions in the said first position” lacks antecedent basis for the terms "said transversal dimensions". It is unclear what is

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meant by the term "correspondent dimensions". Examiner believes Applicant may have intended to state "corresponding dimensions". Further, it is unclear what is meant by the term "effectively bigger". The term "effectively" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 55, the limitation "a dilating portion having an extendable transversal dimensions, protruding distally of said cannula passageway portion, therewith in the initial state a cross-sectional area within the limits of an overall outer contour of said dilating and distal portions along their full length is considerably less than one of said cannula passageway portion" contains many issues. It is not grammatically correct. The term "considerably less" is not defined by the claim, because it is not known what is "considerably less" rather than just "less". The overall outer contour and full length do not have antecedent basis. It is unnecessarily wordy and it is not clear to the Examiner what Applicant is intending to claim with this limitation.

Claim 55 recites the limitation "said guide" and "said complete opening". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39- 51 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US Patent 5,882,340).

Claim 39, 50, 51: Yoon'340 discloses a device containing a cannula (26) with a housing (28) and a tubular passageway portion (30); a dilating means (Figure 2) having a distal portion (34) and a dilating portion (40). The dilating portion (40) has a changeable geometry with a first position (Figure 6) and a second position (Figure 7). The device also contains an actuating means for transposing the dilating portion between the first and second positions (column 7, lines 23-28).

Claim 40, 47: Yoon'340 discloses a carrier (32) having a distal end and a proximal end with a housing (50). There are movable dilating members (44) connected to the distal end. The carrier is adapted for placement inside the cannula and has a carrier attachment allowing removable attachment of the carrier to the cannula (see Figure 1).

Claim 40, 49 (different interpretation than the rejections to claims 40, 47 above): Yoon'340 discloses a carrier (26) with a distal end (34) and a proximal end with a housing (28) and a movable dilating member (40) connected to the distal end. The carrier and the cannula are the same part.

Claim 41, 42, 44: Yoon'340 discloses a penetrating means (60) having a sharp element (66). In the first position, the penetrating means protrudes distally of the distal portion of the dilating means (Figure 6).

Claim 43: The penetrating means has a shield (46) and a biasing spring (45).

Claim 45, 46: Yoon'340 discloses a guide (60, 66) for inserting the dilating portion into the body. The dilating portion contains an axial passage through which the guide passes (Figures 1 and 2).

Claim 48: Yoon'340 discloses a latch mechanism (56) allowing engagement and disengagement of the carrier (32) and the cannula housing (28).

Claim 54: Yoon'340 discloses a device containing a cannula (26) with a housing (28) and a tubular passageway portion (30); a penetrating means (60) having a sharp element (66); a dilating means (Figure 2) having a distal portion (34) and a dilating portion (40). The dilating portion (40) has a changeable geometry with a first position (Figure 6) and a second position (Figure 7). In the first position, the penetrating means protrudes distally of the distal portion of the dilating means (Figure 6). The device also contains an actuating means for transposing the dilating portion between the first and second positions (column 7, lines 23-28).

Claim 55, 56: Yoon'340 discloses a method that includes the use of a dilating trocar, as claimed (see rejection for Claims 55 above). The method includes inserting the dilating portion and cannula portion into a body opening (Figure 6), and removing the actuating means from the interior of the cannula (Figure 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 52, 53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon'340, as applied to Claims 51 and 55, respectively, further in view of Hasson et al. (US Patent 5,176,697).

Yoon'340 teaches that the dilating means can instead be a balloon (column 10, lines 25-31) but does not disclose further details about the use of the balloon.

Hasson'697 teaches a similar device that contains a balloon (30) with cylinder (38) having a plunger (part of syringe 38) adapted to force liquid from the cylinder and into the balloon to expand it (column 6, lines 25-44). It would have been obvious to one of ordinary skill in the art to substitute the dilating means taught by Yoon'340 with the dilating means taught by Hasson'697 because one skilled in the art would expect both dilating means to perform the same function.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is

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(571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734